CLAIMS

1. A pharmaceutical composition for controlled drug delivery comprising a β-lactam antibiotic and one or more carbomers.
2. The composition of claim 1 wherein said β-lactam antibiotic is in the form of pharmaceutical acceptable hydrates, salts or esters.
3. The composition of claim 1 wherein said β-lactam antibiotic agent is a cephalosporin.
4. The composition of claim 3 wherein said cephalosporin antibiotics are selected from cefdinir, cefditoren pivoxil, cefepime, cefixime, cefoperazone, cefotetan, cefpodoxime paroxetil, cefprozil, cefazidine, ceftibuten, ceftriaxone, cefuroxime axetil, cephalexin, cefaclor, cefadroxil, cefamandole, cefoxitin, cefalothin, moxalactum, cefapirin, ceftizoxime, cefonicid, cephadrine, loracarbef, cefetamet and pharmaceutically acceptable hydrates, salts or esters thereof.
5. The composition of claim 4 wherein said cephalosporin is cefprozil or its pharmaceutical acceptable hydrates, salts or esters.
6. The composition of claim 5 wherein said cefprozil or their pharmaceutical acceptable hydrates, salts or esters comprise an amount from 100 mg to 1000 mg.
7. The composition of claim 5 wherein said cefprozil or their pharmaceutical acceptable hydrates, salts or ester comprise from about 30-90% w/w of the formulation.
8. The composition of claim 1 wherein said carbomers are a mixture of Carbopol 971P® and Carbopol 974P®.
9. The composition of claim 1 wherein said carbomers comprise about 0.1% to 50% by weight of the controlled release composition.
10. The composition of claim 9 wherein said carbomers are present at a concentration from about 5 % to about 50 % comprising of Carbopol 971P in an amount from about 0.1 % to about 20 % by weight and Carbopol 974P in an

amount from about 0.1% to about 30 % by weight of controlled release composition.

11. The composition of claim 1 which further comprises other pharmaceutically acceptable excipients selected amongst water-soluble or water dispersible diluents and lubricants.
12. The composition of claim 11 wherein said water-soluble diluent is selected from lactose, mannitol, glucose, sorbitol, maltose, dextrates, dextrins and the like.
13. The composition of claim 12 wherein said water-soluble diluent is lactose.
14. The composition of claim 13 wherein said lactose amounts from about 5% to about 20% by weight of the formulation.
15. The composition of claim 11 wherein said water dispersible diluent is selected from amongst microcrystalline cellulose, starch, pre-gelatinized starch, magnesium aluminum silicates and the like.
16. The composition of claim 15 wherein said water dispersible diluent is microcrystalline cellulose.
17. The composition of claim 16 wherein said microcrystalline cellulose amounts from about 5% to about 20% by weight of the formulation.
18. The composition of claim 11 wherein said pharmaceutical excipient is either one or a combination of lubricants at a concentration in the range of about 0.2% to 5% by weight of the composition.
19. The composition of claim 11 wherein said lubricant is selected from talc, stearic acid, magnesium stearate, colloidal silicon dioxide, calcium stearate, zinc stearate, hydrogenated vegetable oil and the like.
20. The composition of claim 19 wherein said lubricant is preferably selected from talc, stearic acid, magnesium stearate and colloidal silicon dioxide.
21. The process for the preparation of the pharmaceutical composition comprising mixing together, a β-lactam antibiotic or their pharmaceutically acceptable hydrates, salts or esters; with one or more carbomers and optionally, with one or more water soluble or water dispersible diluents and lubricants to form the blend, and compressing the blend into tablets.
22. The process of claim 21 wherein the blend is compacted into granules.

23. A controlled release composition of β-lactam antibiotic comprising a pharmaceutically effective amount of β-lactam antibiotic, one or more carbomers, a water-soluble and /or water dispersible diluent and pharmaceutically acceptable tablet excipients for controlling the release of β-lactam antibiotic.

24. A controlled release composition comprising a β-lactam antibiotic and a release controlling polymer wherein the C_{max} is substantially the same as that of a single dose of an immediate release formulation.

25. A controlled release composition of claim 24 wherein the β-lactam antibiotic is cefprozil

26. A controlled release composition comprising a β-lactam antibiotic and a release-controlling polymer wherein the T > MIC at 0.25 mcg/ml was achieved for about 75% of the dosing interval and T > MIC of 2 mcg/ml was achieved for almost 49% of the dosing interval.

27. A controlled release composition of claim 26 wherein the β-lactam antibiotic is cefprozil.

28. A controlled release composition comprising from about 30- 90 % w/w of cefprozil and from about 0.1-50 % by weight of one or a mixture of carbomers and optionally one or more pharmaceutically acceptable excipients selected from amongst diluents and lubricants.

29. A controlled release composition of claim 28 preferably comprising from about 40-80%w/w of cefprozil and from about 0.1-40 % w/w of one or a mixture of carbomers and optionally one or more pharmaceutically acceptable excipients selected from amongst diluents and lubricants.

AMENDED CLAIMS
[received by the International Bureau on 28 January 2005 (28.01.05);
original claim 1 amended, original claims 2 and 3 deleted, remaining claims renumbered but unchanged. (3 pages)]

1. A pharmaceutical composition for controlled drug delivery comprising a cephalosporin antibiotic and a combination of at least two carbomers.
2. The composition of claim 1 wherein said cephalosporin antibiotic is selected from cefdinir, cefditoren pivoxil, cefepime, cefixime, cefoperazone, cefotetan, cefpodoxime paroxetil, cefprozil, cefazidine, ceftibuten, ceftriaxone, cefuroxime axetil, cephalexin, cefaclor, cefadroxil, cefamandole, cefoxitin, cefalothin, moxalactum, cefapirin, ceftizoxime, cefonicid, cephadrine, loracarbef, cefetamet and pharmaceutically acceptable hydrates, salts or esters thereof.
3. The composition of claim 2 wherein said cephalosporin is cefprozil or its pharmaceutical acceptable hydrates, salts or esters.
4. The composition of claim 3 wherein said cefprozil or their pharmaceutical acceptable hydrates, salts or esters may be present in an amount from 100 mg to 1000 mg.
5. The composition of claim 3 wherein said cefprozil or their pharmaceutical acceptable hydrates, salts or ester may be present from about 30-90% w/w of the formulation.
6. The composition of claim 1 wherein said carbomers are a mixture of Carbopol 971P® and Carbopol 974P®.
7. The composition of claim 1 wherein said carbomers comprise about 0.1% to 50% by weight of the controlled release composition.
8. The composition of claim 7 wherein said carbomers are present at a concentration from about 5 % to about 50 % comprising of Carbopol 971P in an amount from about 0.1 % to about 20 % by weight and Carbopol 974P in an amount from about 0.1% to about 30 % by weight of controlled release composition.
9. The composition of claim 1 which further comprises other pharmaceutically acceptable excipients selected amongst water-soluble or water dispersible diluents and lubricants.
10. The composition of claim 9 wherein said water-soluble diluent is selected from lactose, mannitol, glucose, sorbitol, maltose, dextrates, dextrins and the like.

11. The composition of claim 10 wherein said water-soluble diluent is lactose.
12. The composition of claim 11 wherein said lactose amounts from about 5% to about 20% by weight of the formulation.
13. The composition of claim 9 wherein said water dispersible diluent is selected from amongst microcrystalline cellulose, starch, pre-gelatinized starch, magnesium aluminum silicates and the like.
14. The composition of claim 13 wherein said water dispersible diluent is microcrystalline cellulose.
15. The composition of claim 14 wherein said microcrystalline cellulose amounts from about 5% to about 20% by weight of the formulation.
16. The composition of claim 9 wherein said pharmaceutical excipient is either one or a combination of lubricants at a concentration in the range of about 0.2% to 5% by weight of the composition.
17. The composition of claim 9 wherein said lubricant is selected from talc, stearic acid, magnesium stearate, colloidal silicon dioxide, calcium stearate, zinc stearate, hydrogenated vegetable oil and the like.
18. The composition of claim 17 wherein said lubricant is preferably selected from talc, stearic acid, magnesium stearate and colloidal silicon dioxide.
19. The process for the preparation of the pharmaceutical composition comprising mixing together, a cephalosporin antibiotic or their pharmaceutically acceptable hydrates, salts or esters; with combination of carbomers and optionally, with one or more water soluble or water dispersible diluents and lubricants to form the blend, and compressing the blend into tablets.
20. The process of claim 19 wherein the blend may be compacted into granules.
21. A controlled release composition of cephalosporin antibiotic comprising a pharmaceutically effective amount of cephalosporin antibiotic, combination of carbomers, a water-soluble and /or water dispersible diluent and pharmaceutically acceptable tablet excipients for controlling the release of cephalosporin antibiotic.
22. A controlled release composition comprising a cephalosporin antibiotic and a release controlling polymer wherein the C_{max} is substantially the same as that of a single dose of an immediate release formulation.

23. A controlled release composition of claim 22 wherein the cephalosporin antibiotic is cefprozil

24. A controlled release composition comprising a cephalosporin antibiotic and a release-controlling polymer wherein the T > MIC at 0.25 mcg/ml was achieved for about 75% of the dosing interval and T > MIC of 2 mcg/ml was achieved for almost 49% of the dosing interval.

25. A controlled release composition of claim 24 wherein the cephalosporin antibiotic is cefprozil.

26. A controlled release composition comprising from about 30- 90 % w/w of cefprozil and from about 0.1-50 % by weight of one or a mixture of carbomers and optionally one or more pharmaceutically acceptable excipients selected from amongst diluents and lubricants.

27. A controlled release composition of claim 26 preferably comprising from about 40-80%w/w of cefprozil and from about 0.1-40 % w/w of one or a mixture of carbomers and optionally one or more pharmaceutically acceptable excipients selected from amongst diluents and lubricants.